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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,602	12/12/2003	Hao-Jan Lin	JCLA10516	1741

23900 7590 01/11/2006

J C PATENTS, INC.
4 VENTURE, SUITE 250
IRVINE, CA 92618

EXAMINER

AKHAVAN, RAMIN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,602

Applicant(s)

LIN ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-15 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

- 1. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Independent claims 1 and 11 recite the limitation “the control of the controller” whereby the term “the control” lacks sufficient antecedent basis.

In addition, it is unclear whether “the control” is a structural component of the gene gun apparatus or whether the limitation “the control” is meant to signify an action step taken in practicing the claimed process. The ambiguity is demonstrated by viewing Figure 2 reproduced below:

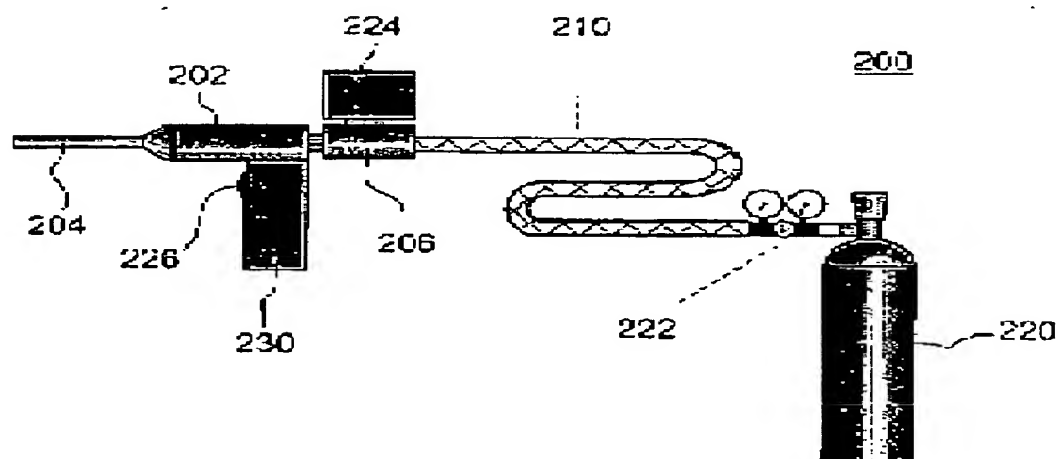


FIG. 2

The structure marked **224** is indicated to be a control valve. The specification further indicates that “the controller” is not pictured thus the figure is not helpful in this regard. (Specification, ¶ 0034; all references to the Specification herein correspond to the published version of the application, i.e., 2004/0180442). The specification provides that “the controller” controls the “control valve **224**. Thus it is unclear whether “the control” is either an additional component or an additional step that controls the controller. If the limitation “the control” is intended to define the “control valve” the claims should be amended to clarify as such. Alternatively, if “the control” is meant to signify an action step of the “control valve” to regulate “the controller” then the claims should be amended accordingly. However, as written the claims are vague because it is unclear how the claims should be interpreted thus rendering indeterminable the claims’ metes and bounds.

In addition, claims 8 and 13 recite the limitation “an outlet” which can be interpreted to mean that there are more than one outlet. This is an embodiment that does not appear to be contemplated by the in the specification. Thus, as written it is unclear whether the limitation should be interpreted to mean a single outlet attributed to *the sprayer* of multiple outlets one which provides at atmospheric pressure of 1. If the former interpretation is intended then it would be remedial to strike the phrase “an outlet of the sprayer” and replace said phrase with “the sprayer’s outlet”.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double

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patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2 and 4-15 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 1-6, 9-10 and 12-22 of U.S.

Patent No. 6,436,709.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method claims are obvious over the reference product/method claims as discussed herein. It should be noted that the instant claims do not exclude micro-particles thus where a reference claim is directed to nucleic acids comprised on micro-particles the limitation for *at least comprising a biological material* (i.e., instant independent claims 1 and 11) is met. Indeed the instant specification contemplates utilizing micro-particles. (e.g., ¶ 134). Further, given the use of the transitional phrase “comprising” in the instant/reference claims, any nucleic acid molecules meet the limitation for virion (which comprises nucleic acids), vaccine (e.g., DNA vaccine) and immunogen (e.g., DNA, such as from bacteria). It is against the preceding backdrop that instant and reference claims are directed to patentably indistinct subject

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matter. In addition regarding instant claims delimiting the discharge speed to *200-300 m/s* it must be noted that supersonic speeds are about 300 m/s.

First as to the reference product claims (1-6, 9-10 and 12-17) it must be noted that the products therein (i.e., the gene gun) is the same gene gun that is utilized in instant methods. Indeed, the reference claims recite the limitation “gene gun” which would immediately alert the ordinary skilled artisan that methods of delivering a gene (i.e., biological material) would be obvious utilization of said gene gun. In any event, the reference claims also provide *a gene transformation method using said gene gun* (i.e. independent reference claim 18). As such, the instant methods of use that exclusively rely on the gene gun of the reference claims are *prima facie* obvious over the product claims. In other words, the instant claims rely on the reference product claims thus are obvious over the same.

Furthermore, in examining certain embodiments in the claims it becomes clear that the instant claims and reference claims are directed to patentably indistinct subject matter. As to the structural components of the gene gun the claims are directed to a *gene gun* comprising a *pressurized chamber, a sprayer, a controller and a material delivery system*. (Compare, instant claims 1 and 11: reference claims 1 and 18). In addition, the sprayer comprises a spray nozzle and tube wherein the nozzle comprises a converging and diverging part so as to increase the discharge speed. (instant claims 1, 11: reference claims 1 and 18).

Further the claims are directed to a biological material, such as nucleic acid molecules. (instant claims 1, 2, 4-6: reference claims 6, 15, 16, 19 and 20). The claims are also directed to discharge speeds that are supersonic. (instant claims 1, 11, 7 and 12: reference claim 18).

Further the pressure at the outlet of the nozzle is about 1 atmospheric (instant claims 8 and 13:

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reference claim 21) and the gas can be helium or nitrogen gas (instant claim 11: reference claim 22). As to instant claim 15, the limitation delimiting the use for a nucleic acid to be delivered does not substantially distinguish from a method of transformation, since nucleic acids have pleiotrophic utility in the field of biotech. In other words, it suffices that both the instant and reference methods are directed to delivery of nucleic acids and it is of little moment how said nucleic acids function subsequently. In sum, in view of the foregoing, the instant claims are obvious over the reference claims.

Relevant Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Loomis et al. (US 6,004,287) teaches a gene gun but said gun does not have the structural requirements as in the instant claims (e.g., spray nozzle comprising diverging-converging aspects). Muehlberger (US 3,914,573) teaches a spray gun discharging a plasma stream at supersonic speeds (e.g., in process of coating a material). LaSalle et al. (US 6,273,789) teaches a device that discharges an abrasive fluid stream onto a surface utilizing a converging-diverging nozzle to produce a supersonic air stream and contemplates utilizing the device for removing material from a biological organism. Finally, O'Brien (US 2004/0033589) teaches a gene gun, which diverges towards an outlet of the gun so as to be cone shaped, but does not teach a barrel that is both converging and diverging.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday-Friday from 8:30-5:30. If attempts to reach

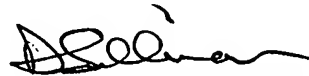
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the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636



DANIEL M. SULLIVAN
PATENT EXAMINER